



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/955,244 | 09/17/2001 | David S. Goldsteen | 293/002DIV2 | 1651 |

1473 7590 03/30/2005

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER

THALER, MICHAEL H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3731

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

87

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/955,244 | Applicant(s) GOLDSTEEN ET AL. | |
| | Examiner Michael Thaler | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) 2-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 14 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3731

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification should be amended to include the claimed terms "elongated guide structure", "longitudinal structure" and "tubular member" and to describe which elements in the drawings these terms refer to.

Claims 2-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5.

Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,429,144). Wilk discloses elongated guide structure (20 or 44 or 56) and longitudinal structure (e.g. the drill described in col. 6, lines 8-13 or the needle 48 or the wire 60), a distal portion of the longitudinal structure adapted to penetrate the side wall of the organ, wherein both the elongated guide structure and longitudinal structure are deflectable toward the side wall (e.g. figures 3B-D, 5A-C or 6A-C). As to lines 20-23 of claim 1, the distal portion of the Wilk longitudinal structure is resiliently biased to deflect laterally toward the side wall (by the curvature of the guide structure 20 or 44 or 56) when released from guidance by the

Art Unit: 3731

guide structure. This is the case since the distal portion of the longitudinal structure, when released from guidance by the guide structure, is deflected laterally by the interaction of the guide structure 20 or 44 or 56 urging a more proximal portion of the longitudinal structure (i.e. a portion of the longitudinal structure that is still within the guide structure 20) laterally. As to claim 16, Wilk discloses a central longitudinal member 60 and a tubular member (one of the dilating catheters 62).

Claims 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,429,144) in view of Yoon et al. (5,800,394). Wilk fails to disclose the distal portion of the longitudinal structure 14 (claim 14) or the tubular member 62 (claim 17) as being externally threaded. However, Yoon et al. teach that a penetrating member P of a tissue penetrating device should have external threads apparently so that it can obtain the advantage of more effectively penetrating tissue (col. 18, lines 1619. It would have been obvious to include external threads on the Wilk structure (14 or 62) so that it too would have this advantage.

Claims 18-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,429,144). Wilk fails to disclose balloons on the guide structure. However, it is old and well

Art Unit: 3731

known in this art to provide balloons on tubular guide catheters and other members in order to obtain the advantages of steering the tip and holding the catheter in place in the body. It would have been obvious to include balloons on the Wilk guide structure 20 so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

Applicant's arguments filed Feb. 16, 2005 have been fully considered but they are not persuasive. The distal portion of the Wilk longitudinal structure (e.g. the portion of needle 48 shown in figure 5A which is distal to the distal end of catheter 44), is oriented laterally (horizontally) as compared with the longitudinal (vertical) orientation of the main portion of the needle 48. This distal portion of needle 48 is resiliently biased to this lateral orientation by the interaction of the curved portion of guide structure 44 and the portion of the needle 48 within the curved portion of guide structure 44. This distal portion of needle 48 is resiliently biased to this lateral orientation even when released from guidance by the guide structure 44 since the distal portion of needle 48 (i.e. the portion of needle 48 which is distal to the distal end of catheter 44) is still oriented laterally as shown in figure 5A

Art Unit: 3731

even though it is released from guidance by the guide structure 44. In other words, the exposed portion of needle 48 is biased laterally (to a horizontal orientation) by the interaction of the curved portion of catheter 44 and the portion of needle 48 within it.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
3/23/05


MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731